

#3



COMBINED DECLARATION AND POWER OF ATTORNEY
FOR UTILITY PATENT APPLICATION

AS A BELOW-NAMED INVENTOR, I HEREBY DECLARE THAT:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: FORMULATIONS OF MOMETASONE AND A BRONCHODILATOR FOR PULMONARY ADMINISTRATION, the specification of which

is attached hereto

X

was filed on August 1, 2001 and assigned Serial No. 09/920,340 and was amended

on _____

I HAVE REVIEWED AND UNDERSTAND THE CONTENTS OF THE ABOVE-IDENTIFIED SPECIFICATION, INCLUDING THE CLAIMS, AS AMENDED BY ANY AMENDMENT REFERRED TO ABOVE.

I acknowledge and understand that I am an individual who has a duty to disclose information which is material to the patentability of the claims of this application in accordance with Title 37, Code of Federal Regulations, §§ 1.56(a) and (b) which state:

- (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
 - (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
 - (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

I do not know and do not believe this invention was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to said application. This invention was not in public use or on sale in the United States of America more than one year prior to this application. This invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on any application filed by me or my legal representatives or assigns more than one year prior to this application.

I hereby claim priority benefits under Title 35, United States Code § 119(e)(1) of any United States provisional application(s) for patent as indicated below. I hereby claim benefit under Title 35, United States Code § 120 of any United States Patent application(s) listed below and, insofar as the subject matter of each of the claims of this application are not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulation, section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

Application No.	Date of Filing (day/month/year)	Priority Claimed
60/223,541	August 4, 2000	Yes <u>X</u> No <u> </u>

I hereby appoint the following attorneys and agents to prosecute that application and to transact all business in the Patent and Trademark Office connected therewith and to file, to prosecute and to transact all business in connection with all patent applications directed to the invention:

Dianne E. Reed, Reg. No. 31,292
J. Elin Hartrum, Reg. No. 43,663
Mark A. Wilson, Reg. No. 43,275
Louis L. Wu, Reg. No. 44,413

. Address all correspondence to Dianne E. Reed at:

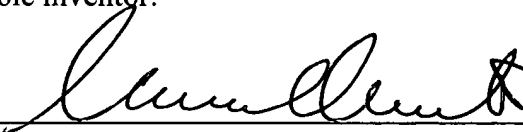
REED & ASSOCIATES
800 Menlo Avenue, Suite 210
Menlo Park, California 94025

Address all telephone calls to Dianne E. Reed at (650) 330-0900.

This appointment, including the right to delegate this appointment, shall also apply to the same extent to any proceedings established by the Patent Cooperation Treaty.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

First Joint or Sole inventor:

Signature:  Date: 1 Oct 01
Full Name of Inventor: Leonard W. Kaplan
Citizenship: United States
Residence: Brookline, Massachusetts
Post Office Address: 559 Boylston Street, Brookline, Massachusetts 02445

Second Joint inventor:

Signature: Karl P. Weinrich Date: 9/27/01
Full Name of Inventor: Karl P. Weinrich
Citizenship: United States
Residence: Bridgewater, Massachusetts
Post Office Address: 413 Spruce Street, Bridgewater, Massachusetts 02324

Third Joint inventor:

Signature: Theodore L. Iorio Date: 9/27/01
Full Name of Inventor: Theodore L. Iorio
Citizenship: United States 9/27/01
Residence: Millis, Massachusetts
Post Office Address: 36 Forest Lane, Milis, Massachusetts 02054

Applicant: Leonard W. Kaplan *et al.*

Serial No.: 09/920,340

Filed: August 1, 2001

Title: FORMULATIONS OF MOMETASONE AND A BRONCHODILATOR FOR PULMONARY ADMINISTRATION

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN

I hereby declare that I am:

the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: LONGWOOD PHARMACEUTICAL RESEARCH, INC.

ADDRESS OF CONCERN: 179 Longwood Avenue, Boston, Massachusetts 02115

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 37 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the person employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled FORMULATIONS OF MOMETASONE AND A BRONCHODILATOR FOR PULMONARY ADMINISTRATION by inventor(s) Leonard W. Kaplan, Karl P. Weinrich, and Theodore I. Iorio described in:

the specification filed herewith.

☒ application serial no. 09/920,340 filed August 1, 2001☐ patent no. , issued .

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or by a nonprofit organization under 37 CFR 1.9(e).

NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME:

ADDRESS:

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME:

ADDRESS:

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

SIGNATURE

NAME OF PERSON SIGNING: Karl Weinrich

TITLE IN ORGANIZATION OF PERSON SIGNING: Vice President and Treasurer

ADDRESS OF PERSON SIGNING: 179 Longwood Avenue, Boston, Massachusetts 02115

DATE:

9/27/01